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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/496,231	02/01/2000	Jeffrey A. Hubbell	50154/002002	5903

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1651

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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/496,231	Applicant(s) HUBBELL ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 18, 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/4/2007</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Declaration***

The Declaration filed on May 18, 2007 under 37 CFR 1.131 has been entered and considered to the extent of the exhibit/evidence presented therein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 and 11,13, 16, and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31,32,and 47-52 of copending Application No. 10/297229. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims of the instant Application appear to be coextensive and overlapping in scope with the method claims of the '229 Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claim 5 is objected to because of the following informalities:

The term “said unsaturated bond or group is not a” appears to be a typographical error of the term “said unsaturated bonds or groups are not” as the phrase to which this phrase is drawn emphasizes the plural form.

Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 13 is redundant to claim 1 as all biomaterials, and all materials, synthetic or naturally-occurring, given the appropriate conditions are “degradable”; and, as such, degradation properties are intrinsic to all biomaterials and to all materials.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “two or more precursor components.. that allow polymerization of the two components..” is unclear. *Two or more* is open language and indicates that additional precursor components are possible. In contrast the phrase “the *two* components” is closed language, conflicts with the “or more” term, and omits the descriptors of “the precursor components”

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which proceed the phrase. Please note that due to other rejections/objections in the claims (see below), Applicant is discouraged from adding the phrase “or more” into the latter phrase without clearly indicating where the support may be found without introducing new matter into the claims.

The term “self selective” is unclear, because the term is not defined by the specification or the claims. Self-selectivity appears to be a critical element defining/distinguishing the method, however, what is selected/not selected, how selection occurs, and how nucleophilic addition correlates to the self-selection/-selectivity reaction is unclear. The claims and specification do not further define self-selective reaction, thus the claims are indefinite as one would not be apprised as to the subject matter embraced by the claims.

The term “accelerator” is unclear, because wherein the independent claim defines a reaction involving a reaction between a conjugated unsaturated bonds/groups and/or strong nucleophiles, it is unclear how a pretreatment with an accelerator (reasonably interpreted as including radical initiators, AIBN, etc.) may preserve the conjugated unsaturated bonds/groups and/or strong nucleophiles character. In particular, it is unclear how the addition of an accelerator which may promote via radical formation (an unpaired electron species) and the polymerized product thereof (radical-polymerized compound, living polymer, etc.) could then support reaction between conjugated unsaturated bonds/groups and lone electron pairs (the defining feature of a nucleophile) the reaction being a nucleophilic addition. Although the above example is a reasonable interpretation to one of skill as to an example of an accelerator and the conflict between radical reactions and nucleophilic addition reactions competing for the same functional groups, ultimately it is unclear what compounds or reagents Applicant intends to define by the use of the term “accelerator” and the specification does not further describe how one would

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determine which compounds are classified as accelerators or how one would determine suitable accelerators consistent with the subject matter embraced by the claims. Thus the metes and bounds of the claims are indefinite.

The term "strong nucleophile" is unclear, because, while the specification discloses thiol or amine nucleophile moieties and *exemplifies* nucleophiles with strength greater than water (specification, page 9), it is unclear which nucleophiles are defined as "strong" nucleophiles, how one would determine degree of nucleophilicity (strong versus weak and gradations therein). Thus one of skill would not be apprised as to the metes and bounds of the claims.

The terms "processed" and "unprocessed" are unclear. It is unclear what defines processed/unprocessed, which compositions may be embraced by processed/unprocessed, or how one would determine a processed versus unprocessed composition (of albumin or naturally occurring peptide/protein or polysaccharide).

The term "functionalized" is unclear. Whereas components having functionalized moieties (eg. "functionalized components") possess particular properties and structural features which clearly distinguish the functionalized components, a *method* "wherein components *are* functionalized to comprise.." claims components which are initially un-/minimally-functionalized and then subsequently functionalized through an unclear active step defined as "modifying" (specification, page 11). A method invoking a known composition (component) and an undefined/unclear method step (functionalizing) merely contemplates the desired product but does not clearly define the modifying step(s)/reaction(s) or the path effecting and correlating the initial components with the desired product(s). It is unclear how one would determine which compounds are capable of functionalizing and by which method(s) to achieve the desired product component. Thus the metes and bounds are unclear.

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The term “at least three strong nucleophiles or three conjugated unsaturated bonds or conjugated unsaturated groups” is indefinite. It is unclear if “at least” refers to three strong nucleophiles or to each of the species (three strong nucleophiles, three conjugated unsaturated bonds, conjugated unsaturated groups). It is also unclear if the latter use of the term “three” refers to the phrase “three conjugated unsaturated bonds or conjugated unsaturated groups” with emphasis on three bonds, but not necessarily three groups, or, in the alternative, if “three” refers to each of the conjugated or unsaturated bonds or groups. Each is a reasonable interpretation of the claims and each combination of “at least” and “three” with the above species defines a distinct claim. Thus one could not clearly determine the metes and bounds of the claims.

The term “sensitive biological molecule”, defined as “a molecule that is found in a cell, or in a body”(specification, page 12), is indefinite. It is unclear what molecule(s) are necessarily “found” in cells (*eg.* Isotopically enriched dioxygen may be found in cells, etc. but is not naturally present/abundant in cells.); what determines sensitivity; and how sensitive is resolved from insensitive. Thus one would not be apprised as to what compounds the phrase “sensitive biological molecules” embraces and the metes and bounds of the claims cannot be determined.

For the reasons above, the claims are rendered indefinite.

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. A method of making a composition minimally requires the active steps of adding/contacting the reagents; reacting the reagents in a step that correlates the starting material to the product produced; and a concluding active step of producing/isolating the produced product. In the instant claims, the omitted step is the active step of producing (and, if necessary, isolating) the biomaterial/hydrogel product.

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No Claims are allowed.

Conclusion

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Examiner
Art Unit 1651



SANDRA E. SAUCIER
PRIMARY EXAMINER

